DURAPLANT® 2.2

Instruction for use

1. General information

The Duraplant 2.2 Implant System may only be applied by dentists and physician who have absolved the training in implantodontics and possess a sufficient amount of expertise. The supra-structures may only be manufactured by trained dentists and dental technicians.

The following instructions are not sufficient for the immediate application of the Implant System.

As the Duraplant 2.2 implants are part of a total concept, only original components and instruments may be utilised in accordance with the instructions and recommendations of the manufacturer. The manufacturer rejects any responsible if foreign products are utilised.

The dentist is responsible to select a suitable implant system for his patient and to apply it expertly.

It is urgently recommended to have an experienced colleague issue instruction regarding the handling of the Implant System (supervision) and/or participate in a Duraplant 2.2 application training.

Please follow FB 013-MD User Manual Duraplant 2.2

2. Overview of Duraplant 2.2-Implant System

The Duraplant 2.2 Implant System comprises two-phase implants, dental tools, instruments, drills and an OP-tray which contains a complete set of instruments structured according to the logic of the process sequence.

The system is colour-coded as follows: red Ø 3.2 mm, green Ø 3.6, blue Ø 4.1 mm; yellow Ø 4.7 mm, grey 5.4 mm.

The instruments are laser-inscribed with the following information: drill: Ø and length, die: Ø and length, countersink: Ø

1. Description of the implants

Duraplant 2.2 two-phase implant. The anatomically shaped implant is equipped with a self-shaping thread, but can also be processed with a pre-cut thread.

Duraplant 2.2 implants are available in the following variations:

REF	Article description
13209	Duraplant 2.2 Implant D 3.2, L 9.0
13210	Duraplant 2.2 Implant D 3.2, L 10.5
13212	Duraplant 2.2 Implant D 3.2, L 12
13213	Duraplant 2.2 Implant D 3.2, L 13.5
13215	Duraplant 2.2 Implant D 3.2, L 15
13309	Duraplant 2.2 Implant D 3.6, L 9.0
13310	Duraplant 2.2 Implant D 3.6, L 10.5
13312	Duraplant 2.2 Implant D 3.6, L 12
13313	Duraplant 2.2 Implant D 3.6, L 13.5
13315	Duraplant 2.2 Implant D 3.6, L 15
13409	Duraplant 2.2 Implant D 4.1, L 9.0
13410	Duraplant 2.2 Implant D 4.1, L 10.5
13412	Duraplant 2.2 Implant D 4.1, L 12
13413	Duraplant 2.2 Implant D 4.1 L 13.5
13415	Duraplant 2.2 Implant D 4.1, L 15
13509	Duraplant 2.2 Implant D 4.6, L 9.0
13510	Duraplant 2.2 Implant D 4.6, L 10.5
13512	Duraplant 2.2 Implant D 4.6, L 12
13513	Duraplant 2.2 Implant D 4.6 L 13.5
13515	Duraplant 2.2 Implant D 4.6, L 15
13609	Duraplant 2.2 Implant D 5.4, L 9.0
13610	Duraplant 2.2 Implant D 5.4, L 10.5
13612	Duraplant 2.2 Implant D 5.4, L 12
13613	Duraplant 2.2 Implant D 5.4 L 13.5
13615	Duraplant 2.2 Implant D 5.4, L 15

2.2 Materials

NaturaLLock Implants

- calcium carbonate solidified pure titanium *TIMEDUR*
- with *Ticer®-surface or TiWithe®-surface*

Instruments

- calcium carbonate solidified pure titanium TIMEDUR®
- pure titanium
- stainless steel, hardened

All parts are suitable for autoclave.

3. Application

Please follow FB 013-MD User Manual Duraplant 2.2

3.1 Indications

The Duraplant 2.2 implants cover all indications of enossal implants in the upper and lower jaw:

- Single dental prosthesis
- Multiple dental prosthesis
- Provision for toothless jaw.

The prosthetic provision can occur by way of crowns, bridges and prostheses. The abutment can be prepared for the optimal adaptation to the gum margin.

3.2 Contraindications

General medical contraindications:

- Conditions or disorders which seem to make a surgical intervention irresponsible, do not warrant normal healing, question the normal function of the body's immune system or exclude the normal reactivity of the bone.

Local contraindications:

- peri-implant bone wall, volume too thin
- provision with attachments
- axis correction of provision over 21° required

CAVE: Periodontal deceases have to be arrested prior to the implantation by way of hygiene and/or surgical measures. Lack of oral hygiene and lack of patient cooperation are contraindications.

4. Side effects and interactions

Systemic side effects of titanium implants are not known to date.

Possible complications:

- injury of anatomic structures, particularly
- permanent anaesthesia due to damage of N. alveolaris inferior, perforation of nasal cavity or maxillary sinus, perforation of lingual bone wall
- chronic pain in chronological context with the implant
- fractures: bone fracture, implant or instrument fracture, dental prosthesis fracture
- peri-implant inflammations

The treating physician or dentist has to be consulted immediately in case of unexpected pain beyond normal postoperative pain or other complications.

It is known that implants may be rejected or get lost without discernible reasons.

5. Preoperative planning

General medical examination; complete clinical and radiological dental examination; education of patient regarding indications, contraindications and success ratio; education of patient regarding the necessity of regular follow-up examinations, including the establishment of an oral hygiene schedule which, if required, includes a periodontal-surgical restoration; establishment of preoperative and prosthetic overall plan in consultation with the dental technician.

6. Surgical technique

The systems-related surgical technique is imparted in a special Duraplant 2.2 application training. A subtle operation technique in hard and soft tissue is imperative in order to ensure optimal conditions for the implant to be accepted.

CAVE:

Please consider that the length of cut is up to 1.4 mm longer than the implantation depth of the implants.

The following measures are required to avoid thermal pre-preparation trauma:

- reduced revolutions of 500 to
- 800 rpm
- utilisation of sharp drills
- utilisation of Duraplant 2.2 - drills only in ascending order of diameters
- external cooling of drills with sterile sodium chloride solution

The normal period of acceptance in the lower jaw is 3 months and in the upper jaw 6 months.

The implants many only be subjected to load after the expiration of these periods.

7. General handling

Prior to use all instruments have to be carefully cleaned, disinfected and sterilised according to the directives of the Robert Koch Institute. Prior to each surgical intervention a maximum germ reduction must be ensured according to the general hygiene regulations for surgical interventions.

Please follow FB 006-MD processing instructions Duraplant

It is imperative to prevent the contamination of the implants; they should therefore be stored in the sterile packaging until immediately prior to the insertion.

If the manipulation of the implant is unavoidable, the use of titanium tweezers is imperative.

CAVE:

The ratchet has to be dismantled in its individual components directly after usage and must be carefully cleaned and disinfected.

5. Packaging and sterility

The packaging of Duraplant 2.2 implants consists of:

- the non-sterile storage packaging including operating instructions
- the secondary packaging as germ barrier
- the sterile primary packaging

A previously used or non-sterile or contaminated Duraplant 2.2 implant may not be implanted under any circumstances.

Don't use the implant after damage oft he original package!.

The implant cannot be returned to the manufacturer or distributor in case of damage to the original packaging.

STERILE R

Do not re-sterilise!

9. Storage

The originally packaged Duraplant 2.2 implants have to be stored in dry condition at normal room temperature. The implants may not be used after the expiration of the sterilisation expiration date.

10. Traceability and documentation

The implants may be traced based on the article and lot numbers. The implants can be traced from the patient back to the manufacturer by way of adhesive labels on the patient passport and in the patient file.

For forensic reasons the manufacturer recommends the complete clinical, radiological, photographic and statistic documentation.

11. Provision of Duraplant 2.2 implants

Duraplant 2.2 implants are exclusively provided to physicians and dentists. Participation in training through the distributor is urgently recommended.

Manufacturer:

ZL-MICRODENT-ATTACHMENT GMBH & CO. KG
Schützenstraße 6-8,58339 Breckerfeld
Tel.: 0 23 38 - 80 10 Fax: 0 23 38 - 8 01 40

CE 0535

Electronical instruction for us available at www.duraplant.de

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